REMARKS

This Preliminary Amendment is responsive to the final Office Action mailed on January 26, 2007. In particular, it addresses the rejections based on Applicant's earlier publications as rendering the present claimed invention obvious, and the Examiner's characterization and conclusions regarding the fact evidence of Applicant's Rule 132 Declaration.

The foregoing amendment in claim 7 specifies that the microrelief is stable. The argument and evidence of record as to the stability of the present invention, and lack thereof in the prior art, now relate expressly to claim 7 and the claims dependent from it.

Applicant has carefully considered the Examiner's comments in the pending Office Action, but respectfully traverses the rejection of claims 1-5, 7, and 9-28 under 35 USC 103(a) in view of Applicant's European Patent No. 0 217 821 ("EP'821") and applicant's 1991 SPIE article, "Edible Holography," termed by the Examiner, "Begleiter II."

No prior art teaches a pharmaceutical dosage form as claimed. As the Examiner concedes, "Begleiter [EP'821] does not teach the pharmaceutical dosage form comprising [an] active substance." For this the Examiner turns to the Begleiter article, "Begleiter II," citing a discussion on page 104 alleged to teach "a holographic composition for compressed candies, children's vitamins, and form of brand identification." However, this cited passage, "4. Holographic Tablets," teaches a tablet formed of compressed powder. As stated in the cited paragraph on page 104, "Powder is then added and compressed [in a punch] replicating a holographic relief structure on the surface of the tablet." To make these powder candy and vitamin tablets, Begleiter II teaches away from both the end-product decorated confections of Begleiter EP'821 as well as its manufacturing methods and materials. Begleiter II teaches no pharmaceutical with a thermoformable layer, as claimed, nor any special layer that carries a microrelief/diffraction grating. The cited references themselves teach away

from combining their teachings to make pharmaceuticals. It is improper to combine them, with hindsight, to say the present invention is "obvious."

The Examiner also notes that the Begleiter II mentions HPMC. But, as she notes, so does Begleiter EP'821. Neither reference teaches using HPMC to make a pharmaceutical. Begleiter II teaches a direct "cold" compression of a powder. There is no reason to disregard the clear teaching of part 4, page 104, of the "Begleiter II" article to somehow, for some unexplained reason, combine the teachings of these two references.

The Examiner, on page 3 of the Action, finds the Rule 132 Declaration filed on October 19, 2006, to be "insufficient" because it "described [sic] a [sic] product-by-process claims," and "does not show a side-by-side comparison showing unexpected and/or unusual results over the product taught by Begleiter [EP'821]."

The Rule 132 Declaration presents facts that refute the "obviousness" of the present invention given the cited art, and gives evidence of unexpected results. The principal unexpected results described are that a workable microrelief/diffraction grating can be thermoformed onto a pharmaceutical and that the resulting microrelief is stable. If the visual image or effect created by the microrelief/diffraction grating is lost (not stable) during the normal product life of the pharmaceutical dosage form, it is not a viable product. The Declaration presents uncontradicted fact evidence that the prior art products had microreliefs/diffraction gratings that were not stable. The cited Begleiter II reference itself says clearly that the holographic effects lasted "9 months or less" (Decl. ¶11; Begleiter II, ¶105).

Applicant is not certain what the Examiner has in mind by the phrase "side-by-side comparison," but as understood, this is exactly what the Declaration does -- it compares the structure and operation, over time, of the products taught by Begleiter (EP'821) and Begleiter II with the present claimed invention. The Declaration is very clear that the prior art (including the only express reference to a pharmaceutical product with a holographic pattern, the Part 4 cold compressed powder product) were not "stable" as claimed here. The present claimed pharmaceutical dosage form with a

stable holographic pattern is a dramatic, basic, and unexpected result. It took years of work, as detailed by the Applicant and author of both of the cited references, to discover the present claimed invention with a stable pattern, and that for the first time provided a commercially viable pharmaceutical dosage form. The factual evidence of record refutes the allegation of obviousness. As a matter of law, if the factual statements are not refuted, they must be taken as true. The pending claims are patentable and should be allowed.

The Examiner also references an April 12, 2006 telephone interview. The undersigned notes an interview summary form. There is no reference to a Rule 132 Declaration, and the undersigned does not recall such.

However, this interview was part of a series of telephone calls on this case. As reflected in the April 12, 2006 fax transmission to the Examiner, in a telephone call on April 7, 2006, there was a suggestion of an Examiner's Amendment, and a follow on call of April 11, 2006. In response to those calls, Applicant send the April 12 fax, together with a proposed set of claims 29-52 amended to present them in "product-by-process" format. The fax transmittal confirmed that he "understands that these Amendments, if acceptable, will place this application in condition for allowance with claims 1-5, 7, and 9-28 as presented by the Preliminary Amendment filed January 25, 2006, and the accompanying [with the April 12, 2006 fax] claims 29-52. Applicant agrees to an Examiner's Amendment of presently withdrawn claims 29-52 in the form attached."

The Examiner suggested that product-by-process claims be added to the application. They were per a proposed Amendment filed on April 12, 2006 by fax. The undersigned does not recall a discussion of a Rule 132 Declaration. None was submitted. The new product-by-process claims, and the then pending claims 1-5, 7, and 9-28 were deemed allowable. Applicant understood that that allowance was later questioned by a Quality Assurance review, which cited the Begleiter prior art discussed above. For the reasons advanced in last Response and in view of this Response, the

evidence of the art itself, the specification herein, and the Rule 132 Declaration, Applicant urges that the pending claims are indeed novel and patentable over this art.

Applicant's Rule 132 Declaration discusses the prior art and the processes it teaches. It does so not, as suggested by the Examiner in the Action, because the claims are, or should be, in a product-by-process form, but rather to explain the prior art, its deficiencies as references herein, and detail that in fact it was not "obvious" for one skilled in this art, as Mr. Begleiter certainly is, to produce the present invention. The present situation is unusually strong, because 1) the disclosures of these references were not merely hypothetically before the inventor, but were in fact known to the inventor, and 2) the Declaration herein presents evidence of what in fact was done, and was or was not "obvious, to a real person skilled in the art prior to, and at the time of, the invention herein.

The Declaration also presents evidence of secondary *Graham v. Deere* factors in addition to unexpected results that support patentability.

The Action also fails to even address the repeated arguments by Applicant that many dependent claims define features that are novel, important, and patentable.

Applicant is not aware of any reasoned application by the Examiner of the cited prior art as teaching or suggesting the features defined by claims 3-5, and 19-24 with respect to a controllable stability that gives a visual indication of the environmental history of the product. These claims are clearly allowable.

A heat fusion bond that avoids a troublesome adhesive layer (claims 15 and 16) is significant, not in the prior art, and patentable. (Indeed, as noted in the specification and in the prosecution herein, conventional wisdom teaches against using heat to manufacture a pharmaceutical because of its adverse effect on active ingredients. Use of thermoforming material and a thermoformable material is contrary to the accepted wisdom. The 132 Declaration herein makes it clear that a thermoformable material as a constituent of a pharmaceutical dosage form is therefore contrary to the conventional wisdom.) Claims 15 and 16 are clearly allowable.

Forming a capsule as a holographic layer is novel, significant, and patentable (claim 17). It should be allowed.

The strip form of the invention shown in Fig. 10 and defined by claims 1 and 18 is believed to be totally new, significant, and patentable.

The use of waxes to produce a controlled stability is also new, significant, and patentable. Claims 11, 12/11, 13/12, 16, 20 and 21 should be allowed.

The problem of twinning in the context of manufacturing holographic pharmaceutical dosage forms is new. The structural features defined by product claims 2-28 are new, significant, and patentable. They should be allowed.

The prosecution history to date does not provide any reasoned statement as to why these dependent claims, or the specific or any other dependent claim, is not patentable over the art now relied on to reject them.

All of the pending claims are clearly patentable over the art and evidence of record.

A prompt allowance of the application is respectfully solicited.

Dated: July 26, 2007

Respectfully submitted,

By 

Peter J. Manus
Registration No.: 26,766
EDWARDS ANGELL PALMER & DODGE LLP
P.O. Box 55874
Boston, Massachusetts 02205
(617) 517-5530
Attorneys/Agents For Applicant